



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/415,540 10/08/99 HAWKINS P PF-0148-2-DI

HM22/0619

Legal Department
Incyte Pharmaceuticals, Inc.
3160 Porter Drive
Palo Alto CA 94304

EXAMINER

SLOBODYANSKY, E

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

06/19/01

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/415,540

Applicant(s)
Hawkins et al.

Examiner
Elizabeth Slobodyansky

Group Art Unit
1652



☒ Responsive to communication(s) filed on Apr 18, 2001

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 18-22 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 18-22 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 1 and 18-22 are pending.

Claims 18-22 are under consideration. Claim 1 is withdrawn.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claim 19, with dependent claims 18 and 20-22, is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 19 recites "a naturally-occurring human polynucleotide sequence variant encoding an amino acid sequence having at least 90% sequence identity to the sequence of SEQ ID NO:1".

With regard to a naturally-occurring human polynucleotide sequence variant, there is no description of any mutational site that exist in nature, and there is no

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description of how the structure of SEQ ID NO:2 relates to the structure of any allele including strictly neutral alleles. The general knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of unknown alleles. The nature of alleles is that they are variant structures, and in the present state of the art the structure of one does not provide guidance to the structure of others. The common attributes of the genus are not described. One of skill in the art would not conclude that applicant was in possession of the claimed genus because a description of only one member of this genus is not representative of the variants of the genus and is insufficient to support the claims.

Therefore, a naturally-occurring DNA encoding a polypeptide comprising a sequence having 90% identity to SEQ ID NO:1 lack sufficient written description needed to practice the invention of claims 18-22.

Response to Arguments

Applicant's arguments filed April 18, 2001 have been fully considered but they are not persuasive.

As noted by Applicants in reciting "Guidelines", "functional characteristics when coupled with a known or disclosed correlation between function and structure" may be sufficient to meet the written description requirement (page 4, 1st paragraph). In the instant case said correlation is not disclosed and a DNA encoding functionally

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unrelated proteins are encompassed. Function of said proteins/DNAs is unpredictable. While combination of structural and functional characteristics such as 90% identity and possession of pyrophosphatase activity may sufficiently describe the genus of the encompassed molecules, the structural characteristics alone such as 90% identity without function do not.

Applicants further argue that "[w]hile all such sequences are not explicitly listed, given the amino acid sequence of SEQ ID NO:1 and the exemplary polynucleotide sequence of SEQ ID NO:2, one of ordinary skill in the art could predict all such sequences using the known genetic code" (page 4, penultimate paragraph). The examiner agrees with that and notices that the genus of a DNA encoding SEQ ID NO:1 is not rejected.

Applicants state that "[t]he identification of these naturally-occurring polynucleotides encoding polypeptides variants with at least 90% amino acid sequence identity to SEQ ID NO:1 would be routine for one skilled in the art based on the disclosure of the polypeptide of SEQ ID NO:1 and the p[olynucleotide of SEQ ID NO:1 in the instant application" (page 5, 1st full paragraph). While the identification of said sequences is enabled, the rejection is of written description.

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Conclusion

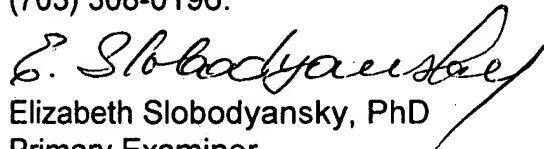
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.



Elizabeth Slobodyansky, PhD
Primary Examiner
June 18, 2001